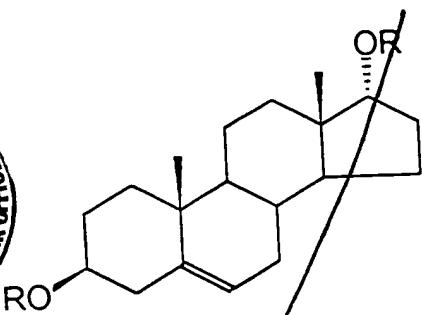
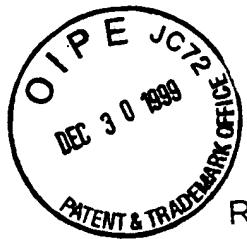


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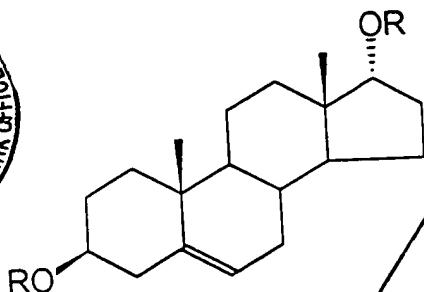


wherein R may be H, alkenyl of 2-8 carbons, alkyl of 1-8 carbons, phenylalkyl of 1-4 carbons, phenyl or COR₂, wherein R₂ may be H, alkyl of 1-8 carbons, alkenyl of 2-8 carbons, phenylalkyl wherein the alkyl has 1-4 carbons (including benzyl) or R₂ may be phenyl, and wherein any phenyl moiety may have up to three substituents chosen from among hydroxy, carboxy of 1-4 carbons, halo, alkoxy of 1-4 carbons, alkyl of 1-4 carbons, or alkenyl of 2-4 carbons and wherein any alkyl may be a straight chain, branched chain, or the alkyl may be wholly or partially cyclized, in a pharmaceutically acceptable carrier, said formulation being in the form of a capsule or tablet.

- W.W.Y.*
16. A composition of claim 15 wherein the composition contains 5-androstan-3 β ,17 α -diol.
 17. A composition of claim 15 in the form of a tablet.
 18. A composition of claim 15 in the form of a capsule.
 19. A composition of matter comprising a tumor proliferation
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inhibiting effective amount of 5-androstene- $3\beta,17\alpha$ -diol or an ester or ether thereof of the formula:



A

wherein R may be H, alkenyl of 2-8 carbons, alkyl of 1-8 carbons, phenylalkyl of 1-4 carbons, phenyl or COR₂, wherein R₂ may be H, alkyl of 1-8 carbons, alkenyl of 2-8 carbons, phenylalkyl wherein the alkyl has 1-4 carbons (including benzyl) or R₂ may be phenyl, and wherein any phenyl moiety may have up to three substituents chosen from among hydroxy, carboxy of 1-4 carbons, halo, alkoxy of 1-4 carbons, alkyl of 1-4 carbons, or alkenyl of 2-4 carbons and wherein any alkyl may be a straight chain, branched chain, or the alkyl may be wholly or partially cyclized, wherein said 5-androstene- $3\beta,17\alpha$ -diol or ester or ether thereof is part of a cyclodextrin inclusion complex.

- 20. A composition of claim 19 wherein the composition contains 5-androstene- $3\beta,17\alpha$ -diol.*



RESPONSE

Claims 1 and 7-14 drawn to methods of treatment have been cancelled. Claim 2-6 drawn to compositions, have been rewritten in accord with the suggestions of the examiner. The claims have been drafted to reflect the verbiage in the claims of the prior issued patent.

Claims 1 and 7-14 were rejected under the doctrine of obviousness-type double patenting as unpatentable over claims of 5,912,240. Those claims have been cancelled from the application.

Claims 2-6, now replaced by claims 15-20, have been rejected under the doctrine of obviousness-type double patenting over the claims of U.S. Patent 5,912,240. Attached hereto is a Terminal Disclaimer signed by the attorney of record and a check in payment for such disclaimer.

Claims 2-6, now replaced by claims 15-20, have been rejected under 35 U.S.C. 103(a) as unpatentable over Tindall, et al. The rejection is respectfully traversed. Tindall only teaches use of various androstenes and androstanes for treatment of the human skin for cosmetic purposes. No composition for use for systemic treatment such as tablets, capsules or cyclodextrin inclusion complexes is taught or suggested therein. Hence, it is urged that compositions claimed in claims 15-20 are not encompassed within the teachings of that reference. Additionally, there is no suggestion in Tindall that any of his compositions should contain cyclodextrin inclusion complexes. Hence, it is urged that the instantly claimed invention is neither taught nor suggested therein.

The Examiner, in the Office Action, suggested the carrier

materials be recited. It is urged that pharmaceutically acceptable carriers for use in tableting and of making capsules are known in the art. What was not known previously was that there as any reason to make capsules or tablets of the 5-androstene-3 β ,17 α -diol, its esters or ethers. Hence, no formulations such as those claimed are suggested previously. Similarly, while cyclodextrin complexes were known, until the invention claimed herein was disclosed, there was no teaching suggesting making any cyclodextrin complexes of the 5-androstene-3 β ,17 α -diol or its derivatives.

It is believed the claims are now in condition for allowance. If discussion would facilitate prosecution of this application, the Examiner is invited to contact the Applicant's representative at (703) 591-4470.



Respectfully Submitted;

A handwritten signature in black ink, appearing to read "Glenna Hendricks".

Glenna Hendricks, Reg. No. 32535